JC10 Rec'd PCT/PTO 2 1 MAR 2005 Approved for use through 3/31/2007. OMB 0651-0021 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL LETTER TO THE UNITED STATES **DESIGNATED/ELECTED OFFICE (DO/EO/US)**

ATTORNEY'S DOCKET NUMBER 701039-52287

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

| COR | ICERNING A SUBMISSIC | 10/528685 | |
|----------|--|--|--|
| | TIONAL APPLICATION NO. PCT/US2003/030466 | INTERNATIONAL FILING DATE 25 September 2003 (25.09.2003) | PRIORITY DATE CLAIMED 27 September 2002 (27.09.2002) |
| TITLE OF | INVENTION METHODS AND C | OMPOSITIONS FOR TREATMEN | |
| APPLICA | NT(S) FOR DO/EO/US CHILDREN | N'S MEDICAL CENTER CORP | ORATION and BENOWITZ, Larry I. |
| Applican | t herewith submits to the United Sta | ates Designated/Elected Office (DO/EO | /US) the following items and other information: |
| 1. 🗓 | This is a FIRST submission of items co | oncerning a submission under 35 U.S.C. 371 | |
| 2. | This is a SECOND or SUBSEQUENT s | submission of items concerning a submission | under 35 U.S.C. 371. |
| 3. X | This is an express request to begin nati (5), (6), (9) and (21) indicated below. | ional examination procedures (35 U.S.C. 371 | (f)). The submission must include items |
| 4. X | The US has been elected (Article 31). | | |
| 5. X | A copy of the International Application | n as filed (35 U.S.C. 371(c)(2)) | · |
| | a. is attached hereto (required | only if not communicated by the Internation | al Bureau). |
| | b. has been communicated by | the International Bureau. | |
| • | c X is not required, as the appli | cation was filed in the United States Receiving | ng Office (RO/US). |
| 6. | An English language translation of the | e International Application as filed (35 U.S.C | . 371(c)(2)). |
| | a. is attached hereto. | | |
| | b. has been previously submit | tted under 35 U.S.C. 154(d)(4). | |
| 7. | Amendments to the claims of the Inte | rnational Application under PCT Article 19 (3 | 35 U.S.C. 371(c)(3)) |
| | a. are attached hereto (requi | red only if not communicated by the Internati | onal Bureau). |
| | b. have been communicated | by the International Bureau. | |
| | c. have not been made; how | ever, the time limit for making such amendm | ents has NOT expired. |
| | d. have not been made and v | will not be made. | · |
| 8. | An English language translation of th | e amendments to the claims under PCT Arti | cle 19 (35 U.S.C. 371(c)(3)). |
| 9. | An oath or declaration of the inventor | (s) (35 U.S.C. 371(c)(4)). | |
| 10. | An English language translation of the Article 36 (35 U.S.C. 371(c)(5)). | e annexes of the International Preliminary Ex | amination Report under PCT |
| Items | 11 to 20 below concern document(s |) or information included: | |
| 11. X | An Information Disclosure Statement | under 37 CFR 1.97 and 1.98. | |
| 12. | An assignment document for recording | ng. A separate cover sheet in compliance with | h 37 CFR 3.28 and 3.31 is included. |
| 13. X | A preliminary amendment. | | • |
| 14. X | An Application Data Sheet under 37 (| CFR 1.76. | |
| 15. 🔲 | A substitute specification. | • | |
| 16. 🔲 | A power of attorney and/or change of | address letter. | |
| 17. | A computer-readable form of the sequ | uence listing in accordance with PCT Rule 13 | 3ter.2 and 37 CFR 1.821- 1.825. |
| 18. | A second copy of the published Interr | national Application under 35 U.S.C. 154(d)(4 | 3). |
| 19. 🔲 | A second copy of the English language | ge translation of the international application | under 35 U.S.C. 154(d)(4). |
| 20. X | Other items or information: Copy - Public References A | shed PCT Cover Sheet - WO 2004/028468 A3; Copy - I NI & A2; Express Mail Cert. Label No. EL 948121594 U | PCT/IB/306; Copy - PCT/IB/308; Copy - PCT/ISA/210 & 220; JS; Check - \$715.00; Return Receipt Postcard. |

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a period to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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JC12 Rec'd PCT/PTC 21 MAR 2005

PTO-1390 (Rev. 02-2005)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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ICATION NO. (if known, see 37 CFR 1.5)

INTERNATIONAL APPLICATION NO.

ATTORNEY OF THE PROPERTY OF THE PR

| U.S. APPLICAT | ION NO. (if know | · |) INTERNATIONAL A | APPLICATION NO. | ATTORNEY'S DOC | KET NUMBER |
|--|---|---------------------------------------|---|-----------------------------|-----------------------------|---------------|
| | 10/528685 PCT/US2003/030466 | | 701039-52287 | | | |
| The foll | owing fees have b | | | | CALCULATIONS | PTO USE ONLY |
| 21. 🔀 Basi | c national fee | · · · · · · · · · · · · · · · · · · · | | \$300 | \$ 300.00 | |
| 22. X Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4) | | | | | \$ 200.00 | |
| | | | | | | · · · · · · · |
| Search fee (37 C Internatio International Sea | nal Searching Aut rch Report prepar | thority ed and provided t | ne international application to the Office | \$100 \$400 | 500.00 \$ | |
| | TOTAL OF 21, 2 | 2 and 23 = | | | \$ 1,000.00 | · |
| sequence lis | sting or computer | program listing file | d in paper over 100 sheets (ed in an electronic medium) paper or fraction thereof. | excluding | | |
| Total Sheets | Extra Sheets | thereof (round i | n additional 50 or fraction up to a whole number) | RATE | | |
| 57 _{- 100} = | -43 /50 = | | | × \$250 | \$ 0.00 | 1 |
| | 0.00 for furnishing ate (37 CFR 1.49 | | ration later than 30 months | from the earliest | \$ 130.00 | |
| CLAIMS | NUME | BER FILED | NUMBER EXTRA | RATE | \$ | |
| Total claims | - | 26 - 20 = | 6 . | x \$50 | \$ 300.00 | |
| Independent clair | ns | 3 -3= | 0 | x \$200 | \$ 0.00 | |
| MULTIPLE DEPE | NDENT CLAIM(S | S) (if applicable) | | + \$360 | \$ 0.00 | ÷ . |
| TOTAL OF ABOVE CALCULATIONS = | | | | | \$ 1,430.00 | î |
| Applicant cla | ims small entity st | tatus. See 37 CFF | 1.27. Fees above are redu | uced by 1/2. | 715.00 | î |
| | | | | SUBTOTAL = | \$ 715.00 | |
| | f \$130.00 for furni ate (37 CFR 1.49 | | translation later than 30 mo | nths from the earliest + | \$ | 0.00 |
| | | L NATIONAL FEE = | \$ 715.00 | | | |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property + | | | | | \$ 0.00 | |
| | | | TOTAL | FEES ENCLOSED = | \$ | 715.00 |
| | ··· | | | 1 | Amount to be refunded: | \$. |
| | | | | | Amount to be charged: | \$ |
| a. X A check | k in the amount of | \$ <u>715.</u> | 00 to cover the at | pove fees is enclosed. | | |
| b. Please charge my Deposit Account No in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed. | | | | | | |
| c. X The Cor Account | nmissioner is here No. 50-0850 | eby authorized to o | charge any additional fees v | vhich may be required, | or credit any overpayment | t to Deposit |
| | | | ARNING: Information on this ard information and authorize | | olic. Credit card informati | on should not |
| | | | CFR 1.495 has not been mon to pending status. | et, a petition to revive | (37 CFR 1.137(a) or (b)) | must be filed |
| BENDALSCER | SESE ONDENCE | ТО: | | 1// | 1/2 / | |
| NIVON DEA BODY LLD | | | | | | |
| 100 Summer Street Roston, MA, 02110, 2131 David, S. Resnick | | | | | | |
| Boston, MA | 02110-2131 | snick | | | | |
| US . | | | | | | |
| | | | <u> </u> | 34,235 REGISTRATION | ON NUMBER | |

Practitioner's Docket No. 701039-52287

PATENT

IN THE UNITED STATES RECEIVING OFFICE

| International Application Number | International Filing Date | International Earliest Priority Date | | |
|----------------------------------|---------------------------|--------------------------------------|--|--|
| PCT/US2003/030466 | 25 September 2003 | 27 September 2002 | | |
| | 25.09.03 | 27.09.02 | | |

TITLE OF INVENTION:

METHODS AND COMPOSITIONS FOR TREATMENT OF

NEUROLOGICAL DISORDER

APPLICANTS FOR DO/US:

CHILDREN'S MEDICAL CENTER CORPORATION:

BENOWITZ, Larry I.

INVENTORS FOR DO/US:

BENOWITZ, Larry I.

VERIFIED CERTIFICATION OF EXPRESS MAILING DATE (INTERNATIONAL APPLICATION (37 C.F.R. section 1.10(c))

I declare that, on <u>March 21, 2005</u> I deposited, with the United States

Postal Service, in an envelope "Express Mail, Post Office to Addressee," bearing Label Number

EL 948 121 594 US, addressed to the "MAIL STOP PCT, Commissioner for Patents, P.O. Box 1450,

Alexandria, VA 22313-1450," and having an express mail certification that I executed, the following papers:

- 1. Transmittal Letter to the U.S. Receiving Office Concerning a Filing Under 35 U.S.C. 371 (in duplicate 4 pp.);
- 2. Application Data Sheet (5 pp.);
- 3. Preliminary Amendment (3 pp.);
- 4. Information Disclosure Statement (2 pp.);
- 5. Form 1449 (2 pp.);
- 6. References A1 & A2;
- 7. Form PCT/IB/308 (1 pg.);
- 8. Published PCT Cover Sheet WO 2004/028468 A3 (1 pg.);
- 9. International Search Report Forms PCT/ISA/220 & 210 (3 pp.);
- 10. Form PCT/IB/306 Notification of the Recording of a Change Attorney's Address (1 pg.);
- 11. Check \$ 715.00; and
- 12. Return Receipt Postcard.

A copy of these papers from the file of this application is attached.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

Date: 2/2/ . 2005

Nidole M. Aguirre

(type or print name of person certifying)